



DECLARATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I re application of: OM DUTT TYAGI

Group: 1624

Serial No: 10/694,619

Examiner: Berch, Mark L.

Filed: October 27, 2003

For: Method of preparation of ceftiofur and salts thereof

Attorney Docket: U014868-8

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Prithvi Ramchandra Upadhyay, a citizen of India declare that:

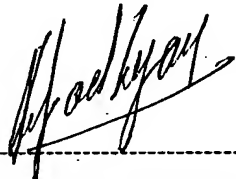
I did my Post Graduation and Doctorate in analytical Chemistry and I am working with Lupin Limited since last 20 years in a capacity of Head Of Department - Analytical Chemistry.

That I have read and understood the specification of US application 10/694,619.

The stability testing of ceftiofur sodium was carried out at a temperature of $40.0^{\circ}\text{C} \pm 2$ at 75% relative humidity wherein the samples are stored in an aluminium container. This study was done as per the International Conference on Harmonized (ICH) guideline for stability testing of new drug substances and products (Q1A (R2)). A copy of the ICH guideline is being attached herewith as Exhibit A. Ceftiofur sodium is a sterile product, which could be easily contaminated, if proper

care is not taken during storage of the sample. Therefore, aluminium container was used to maintain the sterilization of the sample, thereby maintaining the purity of the product.

I hereby declare that all statement made herein of my own knowledge are true and that statements made on information and belief are believed to be true; and further that these statement were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.



Pritish Ramchandra Upadhyay

Signed this 19th day of January 2007.

Enclosure: Exhibit A.